

Chapter 1

Overview

The U.S. Environmental Protection Agency (EPA) has developed a comprehensive, risk-based rule to protect public health and the environment from reasonably anticipated adverse effects of pollutants that may be present in biosolids (sewage sludge) that are used or disposed. Commonly known as the Part 503 rule, the regulation (40 CFR Part 503) was published in the *Federal Register* on February 19, 1993. Much of the rule was based on the results of risk assessments that were scientifically conducted to identify what, if any, risks were associated with the use or disposal of biosolids. Those parts of the rule that were not based on risk assessment were based on performance- or technology-based standards or on management, monitoring, and recordkeeping practices shown to protect human health and the environment.

This guide has been prepared to provide an understanding of the risk assessment process that was conducted as a basis for the Part 503 biosolids rule. The guide illustrates how extensive the process was and how it has resulted in a reasonable and protective rule. The document takes the reader through the multiple-step risk assessment process. Specifically, this guidance document:

- Describes the risk assessment procedures used to develop the Part 503 pollutant limits.
- Provides a historical accounting and discussion of the numerous steps taken to develop the risk assessments.
- Discusses the issues that arose during the risk assessment process and explains how these issues were resolved.
- Explains the assumptions and policy decisions involved in the selection and use of risk assessment data and models and the development of the Part 503 rule.
- Describes the conservativeness of the Part 503 rule and the risk assessment process on which it is based, providing reasons why the Agency believes that the pollutant limits set in the Part 503 rule are protective of public health and the environment and why more restrictive limits are not warranted.
- Addresses commonly asked questions about the risk assessments.

While this guide focuses primarily on the risk assessment conducted for land application of biosolids, it also highlights some of the key features of the biosolids



Safely recycled biosolids can result in healthy lawns and shrubbery, beautiful flowers, and nutritious food.

surface disposal and incineration risk assessments. The guide also briefly discusses the Part 503 non-risk-based requirements. For more detail on the Part 503 risk assessments, consult the appropriate *Technical Support Documents* (U.S. EPA, 1992a, 1992b, 1992c).

The reader will notice that throughout this document sewage sludge is referred to as biosolids. **Biosolids** are the primarily organic solid product yielded by municipal wastewater treatment processes that can be beneficially recycled (whether or not they are currently being recycled). The term biosolids is used in this document to emphasize the beneficial nature of this valuable, recyclable resource (i.e., the use of the nutrients and organic matter in biosolids as a fertilizer or soil conditioner). Also, it is important to point out that while many of the substances found in biosolids are called pollutants throughout this document, many also are beneficial elements that are essential for the growth of plants and animals. The term pollutants has been used as a result of language in the Clean Water Act.

Basis for the Part 503 Risk Assessments

Based on the best scientific data available, established EPA risk guidelines, and the scientific judgment of experts, an extensive risk assessment was conducted for each of the following biosolids use or disposal practices:

- Land application
- Surface disposal
- Incineration

The general process used for conducting the Part 503 risk assessments was based on well-established procedures described by the National Academy of Sciences (NAS, 1983). The procedures are listed in Box 1. Using this process, EPA analyzed risks to humans, animals, plants, and soil organisms from exposure to

Box 1

The Four Steps in the Part 503 Risk Assessments

The risk assessments for biosolids followed these four basic steps:

- **Hazard identification:** Can this pollutant harm human health and/or the environment? Scientists evaluated available studies on the toxicity (harmful effects) of the pollutant being assessed. For example, the hazard identification for biosolids indicated that cadmium does not appear to adversely impact the growth of plants (i.e., does not cause phytotoxicity) but could impact human health via adverse effects on the kidney and other systems if it is present in sufficiently high quantities.
- **Exposure assessment:** Who is exposed, how do they become exposed, and how much exposure occurs? Highly exposed individuals (HEI) were identified and their exposure to pollutants in biosolids were evaluated via relevant pathways of exposure. HEIs included humans, large and small animals, plants, and small organisms. A total of 14 pathways of exposure were evaluated for land-applied biosolids, 2 for surface disposed biosolids, and 1 for incinerated biosolids. The movement of biosolids pollutants through the environment was modeled (using mathematical equations). Many factors influence the actual exposure. For example, organisms often respond differently depending on whether they encounter a pollutant by inhaling it, eating or drinking it, or absorbing it through the skin, and also on where the pollutant goes after it enters the body (e.g., Does it enter the liver via the bloodstream, remaining there to cause liver damage? Or does it move from the liver to another, more sensitive organ where damage might occur?). In addition, an organism's response often differs depending on its nutritional status (e.g., levels of nutrients like iron, calcium, and magnesium can protect against cadmium absorption and retention in the human body), and whether it was exposed to a pollutant for long or short periods.
- **Dose-response evaluation:** If a person, animal, or plant is exposed to this pollutant, what happens? This part of the risk assessment is based on the likelihood of a person, animal, or plant developing a particular disease as the amount (dose) and exposure to a pollutant increases. Such dose-response relationships have been established based on years of carefully conducted toxicological experiments. The biosolids risk assessments used the following EPA toxicity factors, whenever available:
 - Risk reference doses (RfDs)*—daily intake of a chemical that, during an entire lifetime, appears to be without appreciable risk on the basis of all known facts at the time.
 - Cancer potency values (q₁*s)*—conservative indication of the likelihood of a chemical inducing or causing cancer during the lifetime of a continuously exposed individual.
- **Risk characterization:** What is the likelihood of an adverse effect in the population exposed to a pollutant under the conditions studied? This step involves putting the information together from the first three steps. Risk is calculated as:

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

Hazard refers to the toxicity of a substance determined during the hazard identification and dose-response evaluation, and exposure is determined through the exposure assessment.

Generally, three types of risks are identified:

- risks to individuals
- risks to the general population
- risks to highly exposed or highly sensitive subgroups

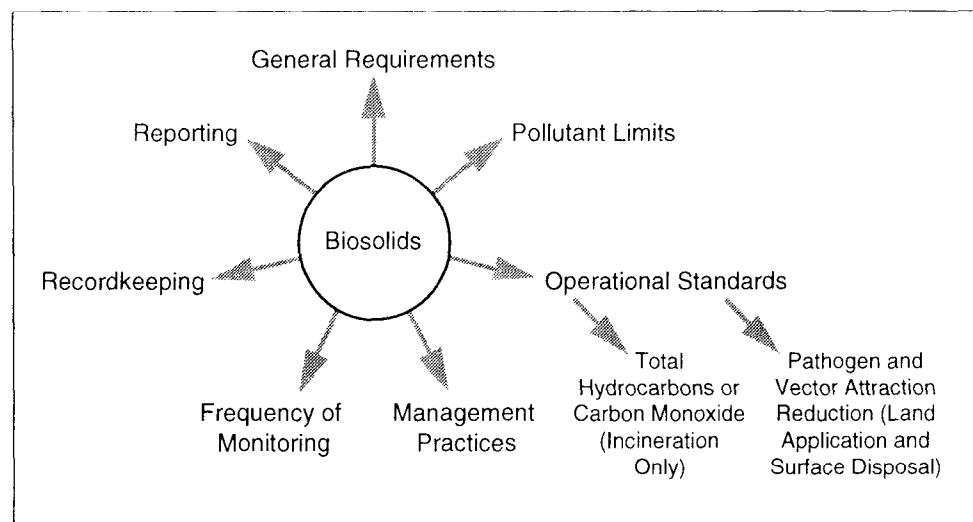
In addition, risk characterization addresses uncertainties associated with some of the information used (e.g., if only studies of animals were available to assess risks to humans, a “safety factor” might be used that multiplies the results by a factor of 10, 100, or 1,000 to adequately protect humans).

pollutants in biosolids through 14 different pathways (e.g., food, water, soil, air) for land-applied biosolids, 2 exposure pathways for surface disposal of biosolids, and 1 exposure pathway for incineration of biosolids. The process of selecting and managing the data, models, assumptions, and approaches used to conduct the risk assessments for the Part 503 rule underwent extensive refinement during the 7 years in which the final rule was formulated.

The Part 503 rule was developed with the realization that the use or disposal of biosolids may result in changes in the environment, as does the use of other fertilizers, the construction of buildings and other structures, and many other aspects of human activity. The biosolids risk assessment process provided a scientific basis for determining acceptable environmental change when biosolids are used or disposed. Acceptable change means that even though changes have occurred as a result of the use or disposal of biosolids (e.g., increases in nutrients and organic matter as well as pollutants), public health and the environment are still protected from reasonably anticipated adverse effects of pollutants in biosolids. This approach is quite different than the policy-driven approach followed by some European countries and Canadian provinces. Those policy-driven approaches allow only small, incremental increases of pollutants from the use or disposal of biosolids over background levels of pollutants already in the environment; for example, metal concentrations may not exceed either the 95th percentile of background soil concentrations, or a specified low concentration level assuming that 100 percent of a person's diet is consumed from biosolids-amended soils under poor management conditions. This latter approach often is not associated with an attempt to determine the extent or acceptability of environmental change.

In addition to using scientific risk assessment methods to identify acceptable environmental change, EPA made policy decisions when necessary to establish pollutant limits for biosolids that protect highly exposed individuals. EPA also relied on best professional judgment based on research and operational data to determine appropriate site restrictions (e.g., requiring waiting periods before harvesting crops grown on soils where biosolids have been applied) and other requirements necessary to ensure the safe use or disposal of biosolids. The end result was the Part 503 rule, which imposes general requirements; pollutant limits; management practices; opera-

Figure 1
Elements of the Part 503 Rule



tional standards (such as technology-based requirements for pathogen reduction and vector control); and frequency of monitoring, recordkeeping, and reporting requirements. These elements of the Part 503 rule are presented graphically in Figure 1.

The basic approach used in the biosolids risk assessments was to identify exposures to highly exposed individuals from pollutants of concern through specific exposure pathways. This approach involved using a combination of “high-end” (conservative) and “mid-range” (average) values to provide conservative protection for highly exposed individuals. This guide provides an explanation of this approach, including how the risk assessment defined highly exposed individuals, why “highly exposed” rather than “most exposed” individuals were ultimately used in the risk assessments, and how the risk-based pollutant limits protect these highly exposed individuals.

The choice of toxicity data, models, and approaches used; the key assumptions and policy decisions made; and the management of data all had important impacts on the risk assessment results. This guide addresses each of these elements, including discussions of science-based and policy-based decisions. Strengths and weaknesses of the risk assessment process also are indicated. One pollutant/pathway analysis is described in detail to illustrate how the various factors involved in the biosolids risk assessments were used to develop pollutant limits.

In conclusion, the best scientific data and talent were assembled and used for developing the final Part 503 rule to ensure that it was based on carefully reasoned science and policy decisions. This comprehensive process resulted in pollutant limits, management practices, and other provisions that protect public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids.

Document Organization

Several sections of this guide provide summaries of the biosolids risk assessment process or key aspects of the process for readers who may want to gain an overall perspective prior to delving into more detailed explanations, also included in this guide. These summary sections include: synopses of the risk assessment process at the beginning and end of Chapter 5; overviews of the many steps involved in the process in Table 1 and Figure 2 (see Chapter 2); a summary of the issues raised during the risk assessments and the resolution of these issues in Table 9 (see Chapter 3); a listing and description of all the parameters used in the risk assessment for land application in Appendices A and B; and a summary at the end of Chapter 4 on the high degree of protectiveness afforded by the Part 503 rule's pollutant limits. Greater detail on the issues raised, their resolution, the determination of pollutant limits, and the development of the Part 503 rule is provided in Chapters 2, 3, 4, and 5, while answers to commonly asked questions are given in Chapter 6.

To help the reader track discussions this guide, letters have been assigned to each individual step and issue listed, as shown in Tables 1 and 9 and in the text of Chapters 2 and 3.

The guide's additional chapters include:

- Chapter 2 describes the extensive process that EPA followed to develop and conduct the risk assessments for biosolids. This description includes a historical listing and discussion of each of the important steps in developing the risk assessments.
- Chapter 3 examines some of the key issues that were raised during the risk assessment process and development of the Part 503 rule and describes how EPA resolved these issues.

- Chapter 4 describes how the risk assessments were conducted, including how scientific data, assumptions, policy decisions, and methods were used. The process of developing the algorithms (i.e., the mathematical equations) used to calculate pollutant limits is discussed, including the different types of parameters used in the algorithms and the values assigned to these parameters. Several example calculations are given for various pollutants and exposure pathways, including a detailed example (for cadmium in Pathway 2 of the land application risk assessment) that explores how the parameters relate to each other and examines the influence of the parameters (both individually and collectively) on the biosolids pollutant limits.
- Chapter 5 summarizes the risk assessment process and discusses how the risk assessment results were used to develop pollutant limits in the final rule. This chapter also includes brief discussions of how different provisions of the Part 503 rule are based on, or support, the biosolids risk assessments. It also provides descriptions of Part 503 provisions that are not risk-based.
- Chapter 6 addresses commonly asked questions about the biosolids risk assessments.
- The Appendices provide additional information used in developing the biosolids risk assessments and Part 503 rule.

